LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
STEPHEN H. McNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
FRANK J. SASINOWSKI
DIANE B. McCOLL
A. WES SIEGNER, JR.
SAMIA N. RODRIGUEZ
ALAN M. KIRSCHENBAUM
DOUGLAS B. FAROUHAR
JOHN A. GILBERT, JR.
JOHN R. FLEDER
ROBERT T. ANGAROLA
(1945-1996)

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329

2603 MAIN STREET
SUITE 650
IRVINE, CALIFORNIA 92614-4260
(949) 553-7400
FACSIMILE
(949) 553-7433

www.hpm.com

MARY KATE WHALEN
OF COUNSEL
JENNIFER B. DAVIS
FRANCES K. WU
DAVID B. CLISSOLD
KATE DUFFY MAZAN
HOLLY M. BAYNE
CASSANDRA A. SOLTIS
JOSEPHINE M. TORRENTE
MICHELLE L. BUTLER
PATRICIA A.A. VANSTORY
THOMAS R. GIBSON

DIRECT DIAL (202) 737-4282

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition pursuant to 21 C.F.R. § 10.30.

A. ACTION REQUESTED

The undersigned requests the following actions from the Commissioner of Food and Drugs:

(1) that the Food and Drug Administration (FDA) publish the date on which the first ANDA with a paragraph IV certification was received for a particular drug on its new website entitled Paragraph IV Patent Certifications as of September 11, 2000, <http://www.fda.gov/cder/ogd/ppiv.htm> (last modified September 19, 2000) (Paragraph IV website);

(2) that FDA adopt a policy whereby, if an ANDA holder should inquire whether it holds the first-filed ANDA with a paragraph IV certification on a drug product, the agency will answer in the affirmative or in the negative, as appropriate, without divulging the name of any other applicants or any other confidential information;

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(3) that, in the case of a drug with several patents, FDA list on its Paragraph IV website the patent(s) to which ANDA applicants have made paragraph IV certifications and the date of the first certification for each patent;

(4) that FDA adopt a policy whereby, if an ANDA holder should inquire whether it holds the first-filed position on a paragraph IV certification for a specific patent, the agency will answer in the affirmative or negative, as appropriate.

B. STATEMENT OF GROUNDS

I. Disclosure of Date on which ANDA is Received

FDA regulations require that the existence of an unapproved new drug application or ANDA not be divulged unless it has been "previously publicly disclosed or acknowledged." 21 C.F.R. § 314.430(b). In its preamble to that regulation, the agency addressed a comment regarding disclosure of the filing of an ANDA.

> One comment asked FDA to provide information as to which ANDA was the first "substantially complete" ANDA. The comment suggested that disclosing such information did not present any confidentiality problems because the ANDA applicant would have revealed the existence of the ANDA when it provided notice of certification of invalidity or noninfringement of the patent to the patent owner and NDA holder.

Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,354 (Oct. 3, 1994). The agency agreed in part with the comment and decided it would disclose the existence of an application, but "in order to preserve the confidentiality of the applicant, [would] not disclose when the application had been received or the applicant's identity." Id. In addition, the agency will not publicly disclose "data or information in the application or abbreviated application" before its approval if its existence has not been made public. 21 C.F.R. § 314.430(c).

We agree with the agency's interpretation of the confidentiality requirements as not allowing FDA to disclose an applicant's identity. We further support the agency's decision in response to the comment not to disclose which ANDA the agency received first, as this would require the disclosure of an ANDA applicant's name. We disagree, however, with the agency's apparent conclusion that "when the application had been received" is

confidential information. The date of receipt of an ANDA cannot possibly be considered confidential by itself. It does not reveal an applicant's name or any details about the drug. Moreover, the date the application is physically received by the agency is not information that is contained "in" the application. It merely reflects the date the Postal Service or other carrier delivered the application to FDA.

As the agency is willing to disclose the existence of a substantially complete application, it should also state the date on which the agency received the application. This information could easily be added to the Paragraph IV website in a new column, alongside the information that already appears on the website.[1]

Adding dates of ANDA receipt to the information published on the Paragraph IV website will promote efficiency by allowing an ANDA holder to determine whether it holds the first-filed ANDA on a particular product. It will be able to plan the manufacture and marketing of its generic drugs more effectively, knowing whether it or someone else is entitled to 180-day exclusivity. Without this knowledge, an ANDA holder is operating blindly. If a sponsor made an incorrectly optimistic assumption regarding its filing position, it could result in a delay of months, if not years, in the prospective launch of the product, the wastage of costly inventories, and a radical shift outward in time of production scheduling and reallocation of other valuable resources. Conversely, if a sponsor held to an inaccurate assumption that it was not the first to file, it could find itself in a position where it, or its suppliers of active pharmaceutical ingredients, have not properly prepared for launch. This would delay the delivery of a generic product to consumers and waste the period of exclusivity to which the sponsor is entitled. Sponsors must make decisions about the purchase of raw materials and the scheduling of manufacturing runs. In addition, they must make informed business decisions regarding investment in extremely costly patent litigation. These decisions are fundamentally affected by whether a sponsor has first-to-file status or must wait for another company's exclusivity to run.

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[1] Beneath its title, the Paragraph IV website states that it will be updated monthly. See Paragraph IV website. A simple comparison of the previous month's website to the current month's will yield any new entries to the website, and hence the month FDA received those applications. The agency is clearly comfortable with allowing this deductive reasoning to find the month the application was received. From a confidentiality standpoint, there is no difference between revealing the actual date of application receipt from what can already be determined from the next update of the website.

II. Disclosure to an ANDA Applicant Whether it was First to File

The agency should also alter its policy of not informing ANDA holders whether they are the first to file. Like the date of an application, whether an applicant is the first to file is not confidential or proprietary information provided by the applicant "in" an application. Thus, it is not subject to the nondisclosure regulations under 21 C.F.R. §§ 314.430(b) and 314.430(c). If a company inquires whether it filed its ANDA first, the agency should give that company an affirmative or negative answer.[2] In providing this information, the FDA would not disclose the names of any other companies that might have filed ANDAs, thus keeping confidentiality intact. As above, the benefits to informing an ANDA holder whether its ANDA was the first to be filed include efficiency in the ANDA holder's planning to manufacture and market as well as providing the ANDA holder the ability and option to focus its financial and technical resources on drugs for which it is eligible for exclusivity.

III. Listing Specific Patents on Paragraph IV Website

In its August 2, 1999 letter responding to petitions for stay of action (PSAs) filed on behalf of American Pharmaceutical Partners, Inc. (APP) and Pharmachemie B.V. (Pharmachemie), the FDA stated, "under the current regulations, eligibility for exclusivity is to be determined on a patent-by-patent basis." Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, to Robert F. Green, Steven H. Sklar, and Kate C. Beardsley, petitioners, 4 (Aug.2, 1999)(Docket No. 99P-1271/ PSA1 and PSA2). Four days later, on August 6, 1999, FDA published a proposed rule, 180 Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, which would allow only one 180-day period of exclusivity no matter how many patents exist on a drug. The proposed rule discussed the same scenario as the APP/Pharmachemie PSAs, in which new patents are listed for the innovator drug after an ANDA with a paragraph IV certification has been filed on the first patent. Until a final rule is published, first-filed ANDAs as to each patent on a drug are apparently eligible for 180-day

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[2] In an informal conversation, an agency official indicated that telling an ANDA holder it was not the first to file would disclose the existence of another application to that ANDA holder. This disclosure is not prohibited by law or regulation, however, as the existence of an ANDA application with a paragraph IV certification is always disclosed to the patent holder and the NDA holder.

exclusivity, even though FDA believes this approach is "unworkable."[3] While we do not agree that FDA's current regulations require patent-by-patent exclusivity, we do agree with FDA that its current position is unworkable.

Given FDA's current position, it is essential that the FDA identify the specific patents that are the subject of paragraph IV certifications. The Paragraph IV website lists drugs to which paragraph IV certifications have been made. It includes the drug name, dosage form, strength, and reference listed drug. It does not, however, indicate to which patent on the drug a paragraph IV certification has been made. As above, this information is not confidential information, as it is disclosed with the notice provided to the patent owner and NDA holder. Therefore, the patent number to which a paragraph IV certification has been made should be posted as another field on the Paragraph IV website, as well as the date on which FDA received the first ANDA with a paragraph IV certification to that patent.

There are clear benefits to listing the specific patent to which a paragraph IV certification has been made. For example, if a drug has three patents and a paragraph IV certification has been filed against one, the other two patents are potential sources of 180-day exclusivity eligibility. Therefore, potential applicants might focus their product development efforts on designing around or challenging the validity of those patents that were not the subject of paragraph IV certifications. This will help accomplish the intended effect of the statute, potentially opening the market to greater generic competition sooner.

IV. Conclusion

The FDA is rightfully concerned about protecting the confidentiality of ANDAs submitted to the agency. But releasing information about the date of receipt of an application with a paragraph IV certification, whether an ANDA holder was first to file, and to which patent a paragraph IV certification has been made, will not violate any of its regulations or any statutes. The agency's Paragraph IV website is a convenient place to list

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[3] The proposed rule recognizes that the statutory framework would support multiple exclusivities, but states that it would "create an exclusivity program that is virtually unworkable in its complexity and which would create even more uncertainty for the industry." 64 Fed. Reg. at 42,876. In the APP/Pharmachemie scenario, the first patent had expired before FDA made its decision on the petitions. Therefore, there was no risk that one company's exclusivity would block another company's exclusivity.

the date upon which the first ANDA was received as well as the patent number to which that ANDA certified. For these reasons, the FDA should take the action requested in our petition.

C. ENVIRONMENTAL IMPACT

The actions herein requested are subject to categorical exclusion under 21 C.F.R. § 25.31.

D. ECONOMIC IMPACT

An economic impact statement will be submitted at the request of the Commissioner.

E. CERTIFICATION STATEMENT

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information to the petitioner which are unfavorable to the petition.

Respectfully Submitted,

Robert A. Dormer

RAD/dad